Exhibit "1"

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

In re American Medical Systems, Inc. Pelvic Repair System Products Liability Litigation — MDL No. 2325

THIS DOCUMENT RELATES TO ALL CASES

PLAINTIFFS' PROPOSED COUNSEL ORGANIZATIONAL STRUCTURE

COME NOW, the Plaintiffs represented by the undersigned counsel, with the unanimous support of the counsel listed hereinbelow, and filed their proposed their Proposed Counsel Organizational Structure in accordance with Paragraph 3 of the Initial Conference and Case Management Order (Pretrial Order No. 1).

Proposed Organizational Structure

As discussed in Section 14.211 of the Manual for Complex Litigation (Fourth), "private ordering" is the recommendation of attorneys with related actions for a particular organizational structure to manage and conduct the litigation, and if adequate to represent the interests of the litigants involved in the proceeding, is one of the methods that Courts have generally used to appoint common benefit counsel in mass tort litigations. In the related context of class action counsel selection, the Third Circuit Task Force on the Selection of Class Counsel observed in its Final Report that "[m]uch of the time [class action plaintiffs' counsel] work out among themselves a voluntary plan to allocate responsibility, often referred to as 'private ordering.'" *Selection of Class Counsel*, Final Report, Section I.D., p. 6.[1] As the Task Force recognized,

[1] This Report is available on-line at: http://www.ca3.uscourts.gov/classcounsel/final%20report%20of%20third%20circuit%20task%20force.pdf (last viewed 3/8/12).

"[c]ase law and experience indicates that the dominant scenario for appointing class counsel is deference to private ordering," further noting that there is generally no reason to consider alternatives to this structure "when the court is presented with qualified counsel who have been chosen through private ordering." Id., Section XII, p. 95.

Private ordering of a proposed organizational structure for the Plaintiffs in these related MDL's is necessary to allow the Plaintiffs to compete on a more level playing field with the Defendants, some of the largest medical device manufacturers in the world. Unlike the Defendants and their counsel, counsel for the Plaintiffs in this litigation must merge quickly to create strategic alliances amongst themselves in order to litigate against several of the world's largest law firms. Without private ordering of counsel structure, the Court is faced with the challenge of selecting from plaintiffs' law firms who are often competing with each other for "market share," and for leadership positions. While it is the Court's obligation to appoint the leadership in these MDL's, the undersigned submit this suggested organizational structure that is being proffered by coordinating and cooperating counsel for Plaintiffs as a proposal to aid the Court. The proposal comes as a result of meetings and much discussion among various counsel representing plaintiffs in these related women's pelvic repair product liability MDLs (MDL 2187; 2325; 2326; and 2327). In circumstances like these related MDL's where a large number of Plaintiffs' counsel have made extensive efforts to organize themselves, the Court's role in the appointment-of-counsel process is hopefully assisted, and perhaps guided by that cooperative effort. The structure proposed herein will avoid the potentially disorganized and inefficient leadership that can result from an organizational structure composed of competing applications.

The undersigned have met and conferred extensively with many of the attorneys who represent or who will represent Plaintiffs in this MDL in an effort to reach a consensus as to a

proposed counsel structure for purposes of this MDL, and for the related MDL's involving similar products (MDL No. 2326 (In re: Boston Scientific Corp. Pelvic Repair Systems Products Liability Litigation) and MDL No. 2327 (In re: Ethicon Pelvic Repair System Products Liability Litigation)).[2] Much thought and work has gone into the organizational structure proposed herein. This structure is the product of numerous meetings and many more conversations by attorneys from across the country who have devoted a substantial amount of time, effort and resources into the investigation and development of these cases, and who are committed to working together for the mutual interests of their respective clients. Counsel who have led these discussions have been actively involved in the leadership of MDL 2187, and also have had extensive experience with mesh litigation pending elsewhere. In crafting these proposals, the experience in managing existing MDL's involving mesh products both in this Court and other courts has been a guide.

Several months ago, a group of attorneys who have been actively involved in the litigation relating to these products began discussing how to address the many problems inherent in having a case involving a single plaintiff implanted with multiple pelvic repair products manufactured by different companies (including the counsel signing this petition, Henry G. Garrard, III, Fred Thompson and Bryan Aylstock). Because of this one-plaintiff/multi-defendant factor, and the multiple factual and legal commonalities in these cases that transcend company lines, it was recognized that having these cases before a singular tribunal made practical sense.[3] Counsel for several women implanted with pelvic repair products sold by AMS, Boston Scientific, and Ethicon/Johnson & Johnson, including the counsel making this proposal,

[2] This proposal also will suggest changes to the leadership structure in the existing MDL 2187 to have all four (4) MDLs operate under a cohesive and consistent structure.

[3] Many of the common factual and legal issues that span these four related MDL's are outlined in the Plaintiffs' Preliminary Position Statement, which is being filed contemporaneously herewith.

ultimately filed separate motions for MDL treatment of those cases seeking transfer to this Court for coordination with the related Bard cases already pending here. In its Transfer Order, the MDL Panel agreed that "[t]he actions in each MDL share factual issues that arise from the allegations of defects in pelvic surgical mesh products manufactured by AMS, Boston Scientific and Ethicon/Johnson & Johnson, respectively," and that this Court "is currently presiding over MDL No. 2187, which involves claims of defects in similar pelvic surgical mesh products." (MDL Transfer Order, p. 2). The Panel further noted that "a number of these actions are brought by plaintiffs who were implanted with multiple products made by multiple manufacturers. Centralization of these three MDLs in one court will allow for coordination of any overlapping issues of fact in such multi-product, multi-defendant actions." Id. For the same reasons that MDL centralization for these three MDL's before this Court was deemed appropriate, these MDL's should have an organizational structure that is cohesive and coordinated across MDL lines.

Each of these MDL's will involve common questions of fact and law that will need to be addressed. For example, all of the devices share a common regulatory lineage, and many of the products at issue in these MDL's are fruit of the same cross-pollinated "family tree" of products. As explained in Plaintiffs' motion filed with the Panel, each of these four manufacturers sought FDA clearance for their respective pelvic repair devices through the FDA's § 510(k) application process, wherein a device is allowed to be marketed if it is deemed "substantially equivalent" to a previously cleared "predicate device" – even if the prior device was marketed by a manufacturer other than the applicant.[4] Several of the AMS, Bard, Boston Scientific, and

[4] A device is "substantially equivalent" to a predicate device if it: "(i) has the same technological characteristics as the predicate device, or (ii) (I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device

Ethicon/Johnson & Johnson pelvic repair products were represented to the FDA to be "substantially equivalent" to products sold by one or more of these other defendants. The interrelationship between these products is but one significant issue that lends itself to coordinated investigation across MDL lines.

The serious health risks generally associated with these women's pelvic repair products also warrant legal inquiry that is not confined to a single product or manufacturer. As discussed in Plaintiffs' MDL motions, the FDA issued public health warnings in 2011 wherein it observed that the serious complications generally associated with these products are not unique to any particular device or company, stating that "[t]he complications associated with the use of surgical mesh for POP repair have not been linked to a single brand of mesh." (See, e.g., Case 2:10-md-02187, Dkt. No. 73-1, p. 1). Plaintiffs submit that the problems associated with transvaginal mesh products are inherent in the use of mesh in the female pelvic region, and thus are not limited to any one product. Instead, these are issues that need to be explored and addressed globally. Many experts for both Plaintiffs and Defendants will traverse company and product lines. The efficient conduct of these cases will require coordination by Plaintiffs' counsel across MDL lines, while still maintaining the four MDL's. Additionally, discovery relating to corporate liability issues will involve common themes, and coordination between the four MDL's will be beneficial.

Finally, the defenses will largely be the same in each MDL, regardless of the product or manufacturer, specifically the "blame the doctor/blame the plaintiff" defense. In September

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contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary…, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device." 21 U.S.C. § 360c(i)(1)(A).

2011, the FDA convened a hearing to discuss safety concerns relating to pelvic repair products.[5] At that hearing, the manufacturers of transvaginal mesh products (including each of the defendants in the respective MDL's now before this Court) were represented by AdvaMed, the world's largest medical technology association representing medical device manufacturers. (See, Excerpt of Transcript of FDA hearing attached hereto as "**Exhibit 1**," p. 132). At the hearing, these manufacturers did not try and differentiate between their respective products – or the reasons that women were experiencing problems. Instead, they asserted the same explanation that the Court can expect to hear in every case in this litigation: "it is the doctor's and/or patient's fault." AdvaMed took the position at the hearing that complications generally associated with all pelvic repair products are the result of patient-related factors and/or factors relating to the doctors who implanted the devices – rather than the products themselves. Dr. Piet Hinoul, Ethicon/Johnson & Johnson's Medical Director for Women's Health and Urology, addressed the Panel on behalf of AdvaMed, Id. at 133 and 140-149, and stated:

> One of the most important questions we need to ask ourselves is also why these adverse events [associated with pelvic repair mesh devices generally] are occurring. And the risk factors for mesh exposures are becoming more and more apparent. Several studies published this year show that hysterectomy, patient age, smoking, diabetes, and surgeon experience predispose patients to mesh exposure.

In light of the interrelationship between the products, the serious health problems generally associated with these devices, and the commonality of the defenses anticipated in every case, a coordinated and unified leadership that spans the four related pelvic repair product MDL's before this Court is essential to the effective and efficient prosecution in these cases.

[5] The legal implications of the FDA Committee's findings and proposals, and the FDA's actions with respect thereto – including the potential reclassification of POP mesh devices, the institution of studies to assess the risks and benefits of vaginal mesh products, as well as expanded post-market monitoring of the performance of these devices – are common issues that will be presented in every case, irrespective of manufacturer.

Several issues relating to damages, causation, and defectiveness of design and manufacturing will be similar as to each MDL defendant for the pelvic organ prolapse products, and likewise with respect to the stress urinary incontinence devices, irrespective of manufacturer. Consequently, cross-MDL coordination will again lead to efficiency.

While it cannot be represented that the proposal herein has the unanimous support of every attorney representing every plaintiff in this MDL or that may become a part of this MDL, the undersigned can represent to the Court that this proposal enjoys a broad consensus among many law firms throughout the country that have participated in the efforts to organize this litigation for several months. The undersigned, as well as the individual counsel listed hereinbelow, unanimously support this proposal.[6] The expeditious, economical and just resolution of these MDL's can best be achieved by a leadership structure composed of counsel who collectively have the willingness and availability to commit to this time-consuming and expensive litigation, and who have the requisite professional experience in handling complex medical device mass tort litigation. Perhaps most importantly, because of the interrelationship between these MDL's in terms of common product defect allegations, similar injuries, and the prevalence of cases involving multiple products by the various defendants, the leadership structure in these MDL's should be composed of attorneys who have the ability and the expressed desire to work with one another in a concerted effort to seek a timely and just resolution of these cases.

As set forth in more detail below, the undersigned propose a Coordinating Co-Lead Counsel, an Executive Committee made up of Co-Leads for each MDL, and a singular PSC all to

[6] The individual attorneys listed in the proposed organizational structure hereinbelow will be filing separate applications in accordance with Paragraphs 18 and 19 of the Initial Conference and Case Management Order (Pretrial Order No. 1).

coordinate across MDL lines. If such proposal is accepted by the Court, then the Coordinating Co-Lead Counsel in conjunction with the Executive Committee will be able to work across MDL lines in conjunction with one PSC to determine which lawyers are best suited to handle a given task, be it common corporate discovery, expert identification, deposition preparation, motions practice and brief drafting, trial teams, and other similar matters that will develop as this litigation progresses. Many of these tasks will not be MDL-specific, but rather will be common issues that will need a coordinated effort. It is also the intent that the Coordinating Co-Lead Counsel will be in a position to determine when separate groups from the PSC should be designated to work on MDL-specific issues that do not cross MDL lines. However, it is vital to this proposal that there be a cohesive and coordinated structure that spans these four related MDL's so as to best achieve the efficiency and effectiveness of representation that will move this litigation forward.

While the size of the proposed Plaintiffs' Steering Committee is large for a typical single MDL, this proposal calls for a singular PSC to coordinate across MDL lines in four separate MDL's, each of which involves a different manufacturer (and related defendants in some cases) and several different products.[7] In light of the number of defendants[8] and products involved in these four MDL's, the size of this PSC is both appropriate and necessary. The undersigned submit that a PSC composed of a significant number of attorneys is necessary to accommodate

[7] Recent product liability MDL's have had large PSC's, such as DePuy ASR (MDL 2197) with 34 attorneys, and DePuy Pinnacle (MDL 2244) with 42 attorneys. These two DePuy hip replacement MDL's both involved a single product and a single manufacturer whereas the four MDL's at issue herein involve multiple different manufacturers (and related defendants), and dozens of related pelvic repair devices. It is anticipated that the number of cases to be filed in the four MDL's will be significantly greater than in both of the hip replacement MDL's combined.

[8] All of these Defendants are represented by large national defense law firms with hundreds, if not thousands of attorneys, all of whom will be coordinating their defense efforts in this litigation.

the large amount of work that will be necessary to prepare these cases effectively, and with many coordinated litigation activities occurring simultaneously across MDL lines. The manpower and womanpower will be essential. The Coordinating Co-Lead Counsel in conjunction with the Executive Committee will be responsible for coordinating the efforts of the members of the PSC.

Based on the foregoing, the undersigned respectfully submit the following proposed counsel structure for the Plaintiffs in this litigation: [9]

COORDINATING CO-LEAD COUNSEL

Bryan F. Aylstock; Henry G. Garrard, III; Fred Thompson, III.

EXECUTIVE COMMITTEE

Bryan F. Aylstock; Tom Cartmell; Clayton Clark; Amy Eskin; Henry G. Garrard, III; Derek Potts; Fred Thompson, III; Aimee Wagstaff.

CO-LEAD COUNSEL, *IN RE: C.R. BARD, INC. PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION* (MDL 2187)

Henry G. Garrard, III; Derek Potts.

CO-LEAD COUNSEL, *IN RE: AMERICAL MEDICAL SYSTEMS, INC., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION* (MDL 2325)

Amy Eskin; Fidelma Fitzpatrick.

CO-LEAD COUNSEL, *IN RE: BOSTON SCIENTIFIC CORP., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION* (MDL 2326)

Clayton Clark; Aimee Wagstaff.

CO-LEAD COUNSEL, *IN RE: ETHICON, INC., PELVIC REPAIR SYSTEMS PRODUCTS LIABILITY LITIGATION* (MDL 2327)

Renee Baggett; Tom Cartmell.

CO-LIAISON COUNSEL

Harry Bell; Paul Farrell; Carl Frankovitch.

[9] The following counsel are listed in alphabetical order.

SINGULAR PLAINTIFFS' STEERING COMMITTEE

David Allen; Tom Anapol; Ben Anderson; Richard Arsenault; Bryan Aylstock; Renee Baggett Lee Balefsky; Harry Bell; Ed Blizzard; Lisa Blue; Riley Burnett; Tom Cartmell; Clayton Clark; Jayne Conroy; Erin Copeland; Martin Crump; A. J. De Bartolomeo; Amy Eskin; Paul Farrell, Jr.; Fidelma Fitzpatrick; Yvonne Flaherty; Wendy Fleishman; Pete Flowers; Carl Frankovitch; Henry G. Garrard, III; Michael Goetz; Tim Goss; Jeff Grand; Todd Harvey; Stacy Hauer; Scott Love; Victoria Maniatis; Dave Matthews; Rick Meadow; Karen Menzies; Mike Miller; Doug Monsour; Mark Mueller; Dianne Nast; Leigh O'Dell; Joe Osborne; Michelle Parfitt; Jerry Parker; Chris Placitella; Derek Potts; Robert Price; John Restaino; Bill Robins; J.R. Rogers; Robert Salim; Joe Saunders; Laurel Simes; Hunter Shkolnik; Fred Thompson, III; Josh B. Wages; Aimee Wagstaff; Ed Wallace; Kim Wilson; Laura Yaeger; Joe Zonies.

This 19th day of March, 2012.

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